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10/658,638

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William D. Lakin

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DOWNS RACHLIN MARTIN PLLC
199 MAIN STREET
P O BOX 190
BURLINGTON, VT 05402-0190

EXAMINER

SAADAT, CAMERON

ART UNIT

PAPER NUMBER

3715

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/658,638

Applicant(s)

LAKIN ET AL.

Examiner

Cameron Saadat

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/16/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 15-28, 30-38 is/are rejected.
- 7) ☒ Claim(s) 12 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9/19/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In response to amendment filed 9/16/2005, claims 1-13 and 15-38 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 13, 15-24, 30-36, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Page (USPN 5,199,877).

Regarding claims 1, 18, 36, and 38, Page discloses a system and method of mathematically modeling pressure dynamics of a body's intracranial system comprising the steps of: dividing the body into a plurality of compartments a simulated heart pump 30, the plurality of compartments including at least one intracranial compartment 1 and at least one extracranial compartment 30 and extracranial veins (Col. 6, lines 30-31), each of the plurality of compartments representing a portion of the body, the simulated heart pump 30 interacting with intracranial compartment 1 (Col. 2, lines 30-65); deriving a plurality of differential flow equations, each of the plurality of differential flow equations governing a pressure dynamic of to one of the plurality of compartments; and solving the plurality of differential flow equations. *Col. 9, lines 25-32; Col. 10, lines 40-44; Col. 13, lines 4-7.*

Regarding claims 2 and 19, Page discloses a method wherein at least one of the differential equations accounts for cerebrovascular autoregulation by the body's sympathetic nervous system (Col. 10, lines 45-55).

Regarding claims 3 and 20, Page discloses a method wherein the plurality of compartments include a plurality of vascular compartments (Col. 2, lines 37-66).

Regarding claims 4 and 21, Page discloses a method wherein the plurality of vascular compartments include a plurality of intracranial compartments (Col. 2, lines 37-66).

Regarding claims 5 and 22, Page discloses a method wherein the plurality of intracranial compartments represent at least one of the intracranial arteries, intracranial capillaries, choroids plexus capillaries, venous sinus jugular veins, and intracranial veins (Col. 2, lines 37-66; Col. 6, lines 12-35).

Regarding claims 6 and 23, Page discloses a method wherein the plurality of vascular compartments include a plurality of central body compartments (Col. 2, lines 46-50).

Regarding claims 7 and 24, Page discloses a method wherein the plurality of central body compartments represent at least one of the central arteries, central capillaries, central veins, and extra-ventricular CSF (Col. 2, lines 37-66).

Regarding claims 13 and 30, Page discloses a method wherein the plurality of compartments include a rest of body compartment (Col. 1, lines 58-62).

Regarding claim 31, Page discloses a method wherein the plurality of differential flow equations include a term representing a pressure flow between compartments. *Col. 9, lines 25-32; Col. 10, lines 40-44; Col. 13, lines 4-7.*

Regarding claim 15, Page discloses a method wherein the plurality of differential flow equations include a pressure driven flows equation (Col. 11, line 20 – Col. 12, line 68).

Regarding claims 16 and 32, Page discloses a method wherein the plurality of differential flow equations include an equation simulating fluid filtration from capillaries into interstitial space (Col. 2, lines 60-66).

Regarding claims 17 and 33, Page discloses a method wherein the plurality of differential flow equations include an equation simulating deformation of the membrane between adjacent compartments (Col. 9, lines 33-68).

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Regarding claims 34 and 35, Page discloses a method of modeling pressure dynamics of an intracranial system comprising the steps of: dividing a body into a plurality of compartments and a heart pump 30, each of said plurality of compartments representing a portion of the body, the heart pump interacting with at least one of said plurality of compartments (Col. 2, lines 37-65); the plurality of compartments including at least one intracranial compartment 1 and at least one extracranial compartment 30 and extracranial veins (Col. 6, lines 30-31), each of the plurality of compartments representing a portion of the body, the simulated heart pump 30 interacting with intracranial compartment 1 (Col. 2, lines 30-65); deriving a plurality of differential flow equations, each of the plurality of differential flow equations corresponding to one of the plurality of compartments (Col. 3, lines 1-35), wherein at least one of the differential flow equations accounts for cerebrovascular autoregulation by a sympathetic nervous system; and solving said plurality of differential flow equations (Col. 10, lines 45-55).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-11 and 25-28 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page (USPN 5,199,877).

Regarding claims 10 and 27, Page discloses a method wherein the plurality of compartments include a non-vascular compartment comprising a tumor (Col. 9, lines 19-22). Page does not explicitly disclose that there is a plurality of non-vascular compartments. However, it is the examiner's position that it would be obvious to one of ordinary skill in the art to modify the non-vascular compartment described in Page by providing a *plurality* of non-vascular compartments, in order to simulate physiological events which occur during the growth of multiple brain tumors.

Regarding claims 11 and 28, Page discloses a method wherein the plurality of non-vascular compartments represent at least one of the lower tissue, brain, ventricular CSF, and extra-ventricular CSF (Col. 9, lines 19-60).

Regarding claim 37, Page discloses a method of modeling pressure dynamics of a body's intracranial system comprising the steps of: dividing the body into a plurality of compartments and a heart pump 30, the plurality of compartments including at least one intracranial compartment 1 and at least one extracranial compartment 30 and extracranial veins (Col. 6, lines 30-31), each of the plurality of compartments representing a portion of the body, the simulated heart pump 30 interacting with intracranial compartment 1 (Col. 2, lines 30-65); each of said plurality of compartments representing a portion of the body, the heart pump interacting with at least one of said plurality of compartments (Col. 2, lines 37-65), wherein a plurality of said plurality of compartments are vascular (Col. 2, lines 37-66) and a compartment that is non-vascular (Col. 9, lines 19-22), the vascular compartments including at least one of the intracranial arteries, intracranial capillaries, choroids plexus capillaries, venous sinus jugular veins, intracranial veins, central arteries, central capillaries, central veins, extra-ventricular CSF, lower arteries, lower capillaries, and lower veins, the non-vascular compartments including at least one of lower tissue, brain, ventricular CSF, and extra-ventricular CSF; deriving a plurality of differential flow equations, each of said plurality of differential flow equations corresponding to one of said plurality of compartments; and solving the plurality of differential flow equations (Col. 10, lines 45-55). Page discloses all of the

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claimed subject matter of claim 37 with the exception of explicitly disclosing that there is a plurality of non-vascular compartments. However, it is the examiner's position that it would be obvious to one of ordinary skill in the art to modify the non-vascular compartment described in Page by providing a *plurality* of non-vascular compartments, in order to simulate physiological events which occur during the growth of multiple brain tumors.

Regarding claims 8-9 and 25-26, Page discloses all of the claimed subject matter with the exception of explicitly disclosing a plurality of lower body compartments that are below the pelvis. However, the examiner takes official notice that the feature of simulating a human body to include body parts below the pelvis is old and well known for providing training to medical professionals. Thus, it would have been obvious to one of ordinary skill in the art to modify the physiological demonstration unit described in Page, by providing simulated human parts that are below the pelvis, in order to provide a realistic simulated human body; thereby providing training.

Allowable Subject Matter

Claims 12 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is an examiner's statement of reasons for allowance:

Patentability is seen in, although not limited to dependent claims 12 and 29, the combination of elements specifically claimed in the system and method for modeling an intracranial system, including the feature of providing an atmosphere compartment that represents a space located outside the body and wherein a differential equation accounts for a pressure of the atmosphere compartment. The closest prior art of record does not teach or fairly suggest this feature in the combination.

Response to Arguments

Applicant's arguments filed 9/16/2005 have been fully considered but they are not persuasive. Applicant emphasizes that Page does not disclose or suggest the feature of deriving a differential equation

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governing a pressure dynamic of a compartment; further purports that Page does not disclose or suggest the derivation of any differential equation corresponding to a compartment of a mathematical model. The examiner respectfully disagrees. It is noted that a differential equation is an equation in which the derivatives of a function appear as variables, wherein a derivative is defined as the instantaneous rate of change of a function. Page discloses a physiological demonstration unit wherein the flow of fluid in and out of a cranial cavity is simulated. This simulation of fluid flow described in Page is realized by calculating differential equations wherein a rate of change of volume of cerebrospinal fluid is the derivative of cerebrospinal volume with respect to time, and wherein the differential flow equations for determining rate of fluid drainage (Col. 9, lines 25-32) govern a pressure dynamic of intracranial pressure PVO. See Col. 10, lines 40-44. In addition, Col. 13, lines 4-7 of Page describes, "Mechanism of cerebral-spinal fluid (CSF) pressure control is described in analog/cat with differential equation based on counter pressures induced by acceleration, velocity & displacement of CSF..."

It is further emphasized by applicant that Page does not disclose or suggest lower body compartments; arguing that the specification describes a lower body compartment as representing a region below the pelvis. In light of this interpretation, the examiner takes official notice that the feature of simulating a human body to include body parts below the pelvis is old and well known for providing training to medical professionals. Thus, it would have been obvious to one of ordinary skill in the art to modify the physiological demonstration unit described in Page, by providing simulated human parts that are below the pelvis, in order to provide a realistic simulated human body; thereby providing training.

Conclusion


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cameron Saadat whose telephone number is (571) 272-4443. The examiner can normally be reached on M-F 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on (571)272-6788. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Cameron Saadat
July 20, 2006

 7/24/06
ROBERT P. OLSZEWSKI
ADVISORY PATENT EXAMINER
EBC CENTER ~~272~~ 3700